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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,266	09/25/2003	Byung Sook Moon	020048-004200US	8805
20350	7590	04/18/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			PANDE, SUCHIRA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,266	MOON ET AL.	
	Examiner	Art Unit	
	Suchira Pande	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12 and 45-53, drawn to a lyophilized bead for amplification comprising a thermally stable enzyme, classified in class 435, subclass 183, for example.
 - II. Claims 13-23 and 54-59, drawn to lyophilized bead for amplification comprising forward and reverse primers, classified in class 536, subclass 24.3, for example.
 - III. Claims 24-44, drawn to methods for amplification by dissolving a lyophilized bead of Gr. I, or Gr. II, in liquid and subjecting the reaction mixture to an amplification reaction, classified in class 435, subclass 91.2, for example.
 - IV. Claims 60-62, drawn to a lyophilized bead comprising a moisture-sensitive reagent, classified in class 514, and subclass 1, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the

Art Unit: 1637

instant case, invention I is for a bead comprising enzyme and invention II is for a bead comprising primers. Both these inventions have a materially different design, mode of operation, function, or effect. Invention of Group I is a bead comprising protein that performs enzymatic function while invention of Group II is a bead comprising DNA.

3. Inventions of Groups I and II are related to invention of Group III respectively as product and process or method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process or method of DNA amplification of Invention III can be practiced with another materially different product such as adding the reagents individually to the reaction mixture instead of using the products of Group I or Group II.

4. These inventions are independent or distinct for the reasons given above, in addition, the inventions fall in different classes and subclasses this would require a different field of search (see MPEP § 808.02). Searching the inventions of Groups I and II; or Groups I and III; and II and III, together would impose serious search burden. A search for thermally stable enzyme will identify enzymes that can be used for any of the metabolic processes such as carbohydrate metabolism etc. in thermally stable organisms. A search for primers could yield primers that can be used for production of arrays or DNA sequencing. Similarly searching for products of Groups I or II would not

Art Unit: 1637

automatically provide information regarding the steps of using these products in method of Group III invention.

5. Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions I, II and III are directed towards products and method of using these products for DNA amplification respectively. Whereas invention IV is directed towards a moisture-sensitive reagent. Since, Inventions I, II and III are all used for amplification of nucleic acid, they have different modes of operation and effects from the invention of Group IV that is used in microanalytic systems unrelated to DNA amplification.

6. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species in claims 7, 11, 21, 22 and 23:

Group I

- a) Polymerase (claim 7 in part);
- b) Ligase (claim 7 in part);
- c) Combination of polymerase and ligase (claim 7 in part); and
- d) Reverse transcriptase (claim 11).

Group II

Art Unit: 1637

A) Bacterial (claim 21 in part), with following species under this group

- i. *Bacillus Anthracis* (claim 21 in part and claim 22)
- ii. *Yersinia pestis* (claim 21 in part and claim 22)
- iii. *Clostridium botulinum* (claim 21 in part and claim 22)
- iv. *Francisella tularensis* (claim 21 in part and claim 22)
- v. Group B *Streptococcus* (claim 21 in part and claim 22)
- vi. *Neisseria gonorrhoeae* (claim 21 in part and claim 22)
- vii. *Chlamydia trachomatis* (claim 21 in part and claim 22)
- viii. *Xylella fastidiosa* (claim 21 in part and claim 22)

B) Fungal (claim 21 in part), and

C) Viral nucleic acid sequences (claim 21 in part) with following species under this group

- ix. *Vaccinia* (claim 21 in part and claim 23)
- x. West Nile Fever virus (claim 21 in part and claim 23)
- xi. Equine Encephalitis virus (claim 21 in part and claim 23)
- xii. Foot and Mouth Disease virus (claim 21 in part and claim 23)

The species are independent or distinct because, they perform very distinct functions in the case of Group I. Whereas in case of Group II the nucleic acid sequences are derived from distinct classes of organisms that cause different diseases in different hosts.

Art Unit: 1637

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 13, and 21 are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non responsive unless accompanied by an election.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

Notice of possible Rejoinder

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

Art Unit: 1637

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

Art Unit: 1637

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERESA STRZELECKA
PATENT EXAMINER

Teresa Strzelecka
4/13/06

Suchira Pande

Examiner
Art Unit 1637